

REMARKS

The present amendment is submitted in response to the Office Action mailed March 18, 2008. Claims 1-26 and 31 are currently pending. By the present amendment, claims 1, 7, 15 and 17 have been amended and claim 31 has been added, claims 27-30 having been previously cancelled. No new issues are presented by these amendments. Prompt and favorable consideration of these claims is earnestly sought.

Claims 7 and 15 were rejected under 35 U.S.C. § 112, second paragraph. By the present amendment, Applicants have amended claims 7 and 15 to correct the lack of sufficient antecedent basis for identified limitation. Therefore, Applicants respectfully request that the rejection of claims 7 and 15 under 35 U.S.C. § 112, second paragraph, be withdrawn.

Claims 1-3, 7-9, 11, 12, 17-20 and 23-25 were rejected under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,827,227 to Delago (hereinafter, "Delago"). According to the Examiner, Delago teaches a sheath system and a method of use substantially as claimed, including a dilation assembly having a handle assembly, and an expansion assembly having a tubular member.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP 2131.01.

Therefore, since Delago does not teach or disclose dilator 12 having threads 50 formed on the tubular member, as required in amended claim 1, nor threads 50 extending the length of the tubular member, as required in amended claim 17, it is respectfully submitted that claims 1 and 17 are patentable over Delago and the rejection of the claims 1 and 17 as being anticipated under 35 U.S.C. §102 over Delago, has been overcome.

Since claims 2-3, 7-9, 11 and 12 depend from claim 1 and claims 18-20 and 23-25 depend from claim 17, and each contains all the features of respective claims 1 and 17, for at least the reasons presented above, claims 2-3, 7-9, 11, 12, 18-20 and 23-25 are also allowable under 35 U.S.C. § 102 over Delago.

Claims 1-9, 11, 12, 14 and 16-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,080,174 to Dubrul et al. (hereinafter, "Dubrul") in view of Delago. According to the Examiner, Dubrul teaches a sheath system substantially as claimed, including a dilation assembly and an expansion assembly; however, as the Examiner duly notes, Dubrul fails to teach that the dilation and expansion assemblies include first and second threads, respectively. As such, the Examiner relies on Delago to teach the use of common first and second threads for attaching components in a sheath system.

As discussed above, Delago fails to teach or disclose the thread being formed on the tubular member. Instead, with reference back to FIG. 1 of Delago, reproduced hereinabove, thread 50 of dilator assembly 12 is formed on housing 14 and not on the tubular member. Thus, Dubrul, taken alone or in any proper combination with Delago, fail to suggest or

disclose a dilator assembly including a tubular member, “the tubular member having an outer surface defining a second thread the second thread being arranged for engaging the first thread defined on the handle assembly,” as substantially recited in amended claim 1. Delago further fails to teach or disclose a method of using a sheath system including, inter alia, the steps of “introducing an expansion assembly having a tubular member with an outer surface defining a second thread extending the length thereof into a dilation assembly having a proximal housing defining an aperture and a first thread in the aperture, the introduction including engaging the first thread with the second thread” as substantially recited in amended claim 17. Therefore it is respectfully submitted that claims 1 and 17 are patentable over Dubrul in view of Delago and the rejection of the claims 1 and 17 under 35 U.S.C. § 103 as being unpatentable over Dubrul in view of Delago, has been overcome.

Since claims 2-9, 11, 12, 14 and 16 depend from claim 1, and claims 18-26 depend from claim 17, and each contain all of the features of respective claims 1 and 17, for the reasons presented above, it is respectfully submitted that claims 2-9, 11, 12, 14, 16, and 18-26 are also allowable.

Claim 10 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Delago or the combination of Dubrul/Delago. As discussed above, neither Delago or Dubrul, taken alone or in any proper combination suggest or disclose all the features of independent claim 1. Since claim 10 depends from claim 1, for at least the reasons claim 1 is patentable, claim 10 is also patentable.

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Dubrul/Delago as applied to the 103(a) claim rejection above, in further view of U.S. Patent No. 6,767,355 to Frova et al. (hereinafter, "Frova"). Frova discloses a tracheostomy dilator for widening a tracheal opening. The tracheostomy dilator includes threads on an outer surface that are configured to engage tissue. There is no suggestion, motivation or teaching to use the tracheostomy dilator for any purpose other than to widen an opening in a trachea. A person of ordinary skill in the art of surgical instrument introduction systems would not look to a tracheostomy dilator having threads for engaging tissue for use with a sheath system including a dilation assembly having a radially expandable tubular sheath. Furthermore, Frova does not provide any disclosure that when taken in any proper combination with Dubrul and/or Delago, teaches the sheath system of claim 1 including a "tubular member having an outer surface defining a second thread the second thread being arranged for engaging the first thread defined on the handle assembly."

By the present amendment, Applicants have added claim 31. Claim 31 depends from claim 1. For at least the reason that claim 1 is patentable over the art of record, claim 31 is also patentable.

In view of the foregoing remarks, Applicants submit that all of the claims are in proper format, are patentably distinct from the prior art of record, and are in condition for allowance.

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The Examiner is invited to contact the undersigned at the telephone number listed below with any questions concerning this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'F. Sardone', written over a horizontal line.

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